IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JUNE BLOCH	:	CIVIL ACTION
Plaintiff,	:	
v.	:	NO. 02-4984
WYETH	:	
Defendant.	:	

O R D E R

AND NOW, this _____ day of _____, 2002, upon consideration of Defendant Wyeth's Motion to Dismiss for Failure to State a Claim, and any responses thereto,

IT IS HEREBY ORDERED and DECREED that said Motion is GRANTED and the Complaint of June Bloch is DISMISSED for failing to state a claim upon which relief can be granted.

BY THE COURT:

_____
THOMAS N. O'NEILL, JR., U.S.D.J.

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WYETH	:	
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DEFENDANT WYETH'S MOTION TO DISMISS THE COMPLAINT OF PLAINTIFF JUNE BLOCH FOR FAILURE TO STATE A CLAIM

Defendant Wyeth hereby moves this Court, pursuant to Federal Rule of Civil Procedure 12(b)(6), to dismiss the Complaint of plaintiff June Bloch for failure to state a claim upon which relief can be granted. The grounds for this Motion are set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

Respectfully submitted,

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DATED: July 24, 2002

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JUNE BLOCH	:	CIVIL ACTION
Plaintiff,	:	
v.	:	NO. 02-4984
WYETH	:	
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MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT WYETH'S MOTION TO DISMISS THE COMPLAINT OF PLAINTIFF JUNE BLOCH FOR FAILURE TO STATE A CLAIM

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DATED: July 24, 2002

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

This case does not belong in court. The filing of the Complaint – within 48 hours of the release of new data from a long-term clinical study involving defendant's hormone replacement drug Prempro™[1] – has more to do with plaintiffs' lawyers racing each other to the courthouse doors than with the legitimate goal of tort litigation, i.e., making plaintiffs whole for injuries they have suffered.

Here, the plaintiff admits that she has no injury and claims only that she "may be" at some unspecified degree of "increased risk of injury" because she used Prempro™ for some unspecified time period (Complaint ¶ 4). On that basis, she purports to represent a class consisting of every woman who has ever used Prempro™ and seeks (1) personal injury damages, (2) purchase price refunds, (3) an order requiring the defendant to "inform the public" of the reported risks of Prempro™, and (4) creation of a court-supervised fund to provide an undefined "medical monitoring" program for some unspecified period of time.

The Complaint should be dismissed. Plaintiff, having suffered no injury, plainly lacks standing to bring any claim for personal injury. Whether filed as an individual suit or denominated as a class action, a plaintiff has no standing to invoke judicial remedies for injuries suffered – if at all – only by others. See, e.g., O'Shea v. Littleton, 414 U.S. 488 (1974).

Nor does plaintiff's demand for "refunds" or disgorgement based on money paid by consumers for Prempro™ give rise to any justiciable legal claim. In addition to admitting that

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1 The study is known as the Women's Health Initiative (WHI) and is sponsored by the National Heart, Lung and Blood Institute in collaboration with other units of the National Institutes of Health ("NIH"). The new data concerning Prempro™ was released by NIH in an article published in the July 17 issue of the Journal of The American Medical Association (JAMA) and was available on-line on July 9 (Complaint ¶¶ 12-19). As stated in the Complaint, new data caused the NIH to terminate the long-term study of Prempro™ on July 8. Id.

Prempro™ never harmed her, plaintiff admits that Prempro™ – which remains on the market and approved by the FDA as "safe and effective"[2] – has been efficacious, i.e., that it effectively replaces hormones lost at menopause and has "thereby reduc[ed] the incidence of post-menopausal symptoms such as hot flashes, night sweats and vaginal dryness" for "millions of women" (Complaint ¶ 8). As courts have recently held, even where a drug has been withdrawn from the market because of safety concerns, a plaintiff who has received the drug's benefits and has suffered no personal injury has no standing to pursue a refund claim on her own behalf or on behalf of anyone else. Rivera v. Wyeth-Ayerst Labs, 283 F.3d 315 (5th Cir. 2002); Lennon v. Wyeth-Ayerst Labs., Inc.,[3] 2001 WL 755944 (Pa. Super. 2001), alloc. denied, 729 A.2d 1253 (Pa. Dec. 17, 2001) (affirming dismissal of refund suit brought by uninjured recipients of childhood vaccine which had been withdrawn from the market).[4]

There is similarly no merit in plaintiff's request for an order requiring defendant to publicize the "dangers" of Prempro™. Certainly plaintiff herself needs no such further communication. Her Complaint attests to her own detailed awareness and sensitivity to the

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2 See 21 C.F.R. § 314.2 (1998).

3 All unpublished opinions and orders cited herein are in alphabetical order in a separately-filed Appendix.

4 Not only is Prempro™ still FDA-approved, still on the market, and admittedly effective in treating post-menopausal symptoms, the WHI data cited by plaintiff also demonstrates Prempro's™ value in combating osteoporosis and colorectal cancer (Complaint ¶ 22). Moreover, the NIH, in announcing the termination of the Prempro™ portion of the WHI study, specifically stated that "for osteoporosis prevention, women should consult their doctors and weigh the benefits against their personal risks for heart attack, stroke, blood clots and breast cancer" and that "women taking the therapy for relief from menopausal symptoms may reap more benefits than risks." WHI, New Facts About Estrogen/Progestin Hormone Therapy ("New Facts") attached hereto as Exhibit A. The Court may consider this NIH publication on a Rule 12(b)(6) motion because it is undisputably authentic and plaintiff refers in her Complaint to the information and news releases developed by the NIH in conjunction with the release of the study results (see Complaint ¶ 19). See, e.g., Rossman v. Fleet Bank Nat'l Ass'n, 280 F.3d 384, 388 n.4 (3d Cir. 2002) (citing Pension Benefit Guar. Corp. v. White Consol. Indus. Inc., 998 F.2d 1192, 1196; In re Burlington Coat Factory Securities Litig., 114 F.3d 1410, 1426 (3d Cir. 1997); In re MBTE Prod. Liab. Litig., 175 F. Supp. 2d 593, 606 n.17 (S.D.N.Y. 2001) (citing Fed. R. Evid. 201(b)(2) and cases).

alleged "dangers" of Prempro™. And she has no standing to pursue the claims – if any – of other Prempro™ users who might lack her own heightened awareness. Moreover, the extent to which drug companies inform physicians and/or patients of the risks and benefits of FDA-approved drugs is thoroughly and carefully regulated by the FDA pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. The "package insert," as well as all forms of direct-to-consumer advertising, are subject to pervasive FDA control and oversight. See 21 U.S.C. § 352 and 21 C.F.R. Parts 201 and 202. The FDA also has ample power and the sole discretion to enforce its regulations, including the power to require drug companies to issue whatever revised warning labels or public notices that might be required. 21 U.S.C. §§ 352(f)(2), 336, and 375; 21 C.F.R. §§ 201.56 and 201.57. The FDA can also issue safety warnings itself if company actions are deemed insufficient. 21 U.S.C. § 375. Moreover, the FDA provides for "citizen petitions" by which members of the public can petition the agency to exercise its authority. See 21 C.F.R. § 10.30. Here, plaintiff has not filed any citizen petition and has no standing to simply usurp the FDA's role as the public's guardian in this regard. See, e.g., Bernhardt v. Pfizer, Inc., 2000 U.S. Dist. Lexis 16963 at *8-9 (S.D.N.Y. 2000) (refusing to consider personal injury plaintiff's request for injunction requiring drug company to inform public and physicians of drug's lack of effectiveness).[5]

Finally, plaintiff's demand for a "medical monitoring" program to administer unspecified tests to every past or present user of Prempro™ also fails to state a viable claim on which relief can be granted. In Pennsylvania, the essential elements of a suit for medical

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[5] In Bernhardt, the court stayed the request for injunctive relief to allow the FDA to consider plaintiff's request while plaintiff's personal injury case continued in court. Here, plaintiff has no personal injury case and has no standing to make a request for injunctive relief. Her Complaint should simply be dismissed.

monitoring relief are carefully spelled out and the Complaint makes clear that they cannot be satisfied here. In Redland Soccer Club, Inc. v. Dep't of the Army, 548 Pa. 178, 696 A.2d 137 (1997), the Pennsylvania Supreme Court held that medical monitoring costs cannot be imposed on defendants without a showing, *inter alia*, that a defendant's "negligence" has caused a plaintiff to be exposed to a "proven hazardous substance," that "as a proximate result of such exposure," plaintiff has a "significantly increased risk" of contracting "a serious latent disease," and that a monitoring procedure exists which not only makes early detection of such latent disease possible, but also is "reasonably necessary" and, perhaps most importantly, is "different from that recommended in the absence of the exposure." Accord Barnes v. American Tobacco Co., 161 F.3d 127, 138 (3d Cir. 1998).

Here, plaintiff's claim for medical monitoring fails, at the pleading stage, for at least three reasons:

First, plaintiff never alleges that Wyeth knew or should have known of the WHI study results which have given rise to this case (Complaint ¶¶ 17-18). A drug company's duty – founded upon negligence principles – is to reasonably inform prescribing physicians of risks of which it is aware or reasonably should be aware. Hahn v. Richter, 543 Pa. 558, 673 A.2d 888 (1996). Because plaintiff does not and cannot allege that Wyeth was negligent in failing to disclose prior to July 2002 information that the NIH did not release until that time, she cannot allege – and the Complaint does not allege – that her "exposure" to Prempro™ was "proximately caused" by Wyeth's negligence. The medical monitoring claim must be denied on that ground alone.

Second, the Complaint fails to allege that plaintiff has a "significantly increased risk" of contracting a serious disease. All that is alleged as to the plaintiff – whose duration of

use is never disclosed – is that she "may" be at some degree of increased risk (Complaint ¶ 4). Such an allegation is clearly insufficient under Redland. Moreover, the WHI data relied upon by plaintiff make it clear that no Prempro™ users could make the requisite allegation, or showing, of "significantly increased risk." The breast cancer data quoted in the Complaint, for example, suggest that long-term use of Prempro™ might increase a woman's annual risk of breast cancer from .30 of 1% to .38 of 1%, an increase of only eight one-hundreths of 1%, hardly the level of "significantly increased risk" which could give rise to establishment of a court-imposed medical monitoring program.

Third, and perhaps most compelling, the Complaint completely fails to address a fundamental element of the cause of action under Redland. The desired monitoring must be "different from that normally recommended in the absence of the exposure." Thus, for example, it is not enough to say that mammograms are useful for the early detection of breast cancer or even that they are "reasonably necessary" for some subset of women. Rather, a plaintiff seeking to shift the cost of such testing to the defendant must allege – and eventually prove – that such testing is "reasonably necessary" because of exposure to defendant's product and is not something that would be appropriate anyway. Here, the Complaint carefully avoids alleging that the monitoring program envisioned for Prempro™ users (which the Complaint never bothers to describe) is somehow "different" from that which would be appropriate for menopausal women who never used Prempro™ (Complaint ¶¶ 72-78). This is not a mere pleading failure. On breast cancer, for example, routine mammography is already standard medical practice for all post-menopausal women. There is no "different" monitoring regime which plaintiff has alleged – or could allege – is medically necessary for Prempro™ users.

Plaintiff's Complaint proves the adage that haste makes waste. In their rush to file something, plaintiff's lawyers have overlooked the most basic principles of standing and justiciability and have utterly failed to satisfy the most basic pleading elements of the claims they purport to bring. Without even reaching the manifest unsuitability of this case for class certification, the Court should dismiss it.

II. ARGUMENT

Plaintiff has no injury, no damages, no standing, and no legally cognizable tort, contract, or statutory theory for her many claims against Wyeth. Because she has no right under existing law to have the Court entertain her claims, each and every count of her no-injury Complaint should be dismissed under Rule 12(b)(6) for failure to state a claim for relief.[6]

A. Plaintiff Has No Standing To Assert Any Of The Claims In Her Complaint

The most glaring infirmity in plaintiff's multi-count Complaint is her inability to plead injury. This is not just a matter of pleading. It is a matter of constitutional standing and presents an incurable threshold deficiency that puts her out of court on each and every one of the claims she asserts.

The concept of standing derives from the fundamental principle that a plaintiff has no right to sue unless she has suffered some legally cognizable injury. Allen v. Wright, 468 U.S. 737, 754 (1984); O'Shea, 414 U.S. at 494. The principle is at the cornerstone of any lawsuit – if

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[6] The Complaint has nine counts, numbered I through X, with no Count IV. Count IX is merely a series of boilerplate assertions regarding intra-corporate liability and does not even purport to state any separate cause of action. Count X purports to assert a claim for punitive damages but there is no separate cause of action for punitive damages under Pennsylvania law. See, e.g., Nix v. Temple Univ., 408 Pa. Super. 369, 380, 596 A.2d 1132, 1138 (1991) (citing Feingold v. SEPTA, 512 Pa. 567, 517 A.2d 1270 (1980)).

a plaintiff has no injury, she has no standing to sue and the Court may not hear her claims. See, e.g., Rivera, 283 F.3d at 318-19; Nye v. Erie Ins. Exchange, 504 Pa. 3, 5, 470 A.2d 98, 100 (1983).

The courts have not hesitated to dismiss claims for lack of standing where the plaintiff has no legal injury. See, e.g., Lauletta v. Transworld Express, Inc., 1998 U.S. Dist. Lexis 17392 at *8-9 (E.D. Pa. 1998) (dismissing plaintiff Palombi's claims because he had no injury and no standing); Robinson v. Vaughan, 1992 U.S. Dist. Lexis 19518 at *2-3 (E.D. Pa. 1992). A plaintiff's purported status as a class representative does not change the analysis. See, e.g., O'Shea, 414 U.S. at 494; In re MBTE Prod. Liab. Litig., 175 F. Supp. 2d 593, 606-11 (S.D.N.Y. 2001) ("Because *La Susa*, the only named plaintiff, had no standing at the time the action was commenced and no class has been certified, the entire *La Susa* action must be dismissed").

As the Rivera court explained, at an "irreducible constitutional minimum" standing has three elements: (1) injury in fact to the plaintiff, (2) a causal connection between the injury and the defendant's conduct, and (3) relief that will redress the injury. 283 F.3d at 318-19 (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992)). Plaintiff does not even get past the first element of the three-part test. She admits that she has used Prempro™ "for a number of years" without injury (Complaint ¶ 4). Moreover, she admits that Prempro™ has been efficacious in replacing hormones lost at menopause, "reducing the incidence of post-menopausal symptoms such as hot flashes, night sweats and vaginal dryness" for "millions of women," and reducing the risk of colorectal cancer and bone fractures (Complaint ¶¶ 8, 22).

Plaintiff cannot hide the fact that she has no injury and no standing by alternatively casting her claims in the boilerplate of tort, contract, equity, or consumer protection

statutes. A plaintiff cannot "plead around" the fundamental requirement of an injury and standing by asserting the same no-injury claims under different theories. See, e.g., Rivera, 283 F.3d at 320-21; cf. Martin v. Ford Motor Co., 914 F. Supp. 1449, 1455 (S.D. Tex. 1996) (granting summary judgment on plaintiff's various tort and statutory counts because they failed to show actual injury); see generally Friends of the Earth, Inc. v. Laidlaw Envntl. Servs. (TOC) Inc., 528 U.S. 167, 180-81 (2000) (plaintiff must demonstrate standing separately for each form of relief sought).

"[O]scillating between tort and contract law claims," the Rivera court observed so incisively, cannot "obscure the fact that [plaintiff] ha[s] asserted no concrete injury. Such artful pleading . . . is not enough to create an injury in fact." Rivera, 283 F.3d at 320-21. The same holds true for plaintiff's inartful and generalized boilerplate pleading. Her pleadings cannot create an injury she does not have or disguise the fact she suffered no cognizable personal or economic harm of any kind from her use of Prempro™. Her Complaint should be dismissed because she cannot even get past the first step of the three-step ladder of standing.

B. Plaintiff Has No Viable Basis Under Pennsylvania Law For Any Of The Claims She Asserts

1. Pennsylvania Law Does Not Recognize A Strict Liability Claim Against Manufacturers Of Prescription Drugs (Count I)

The generalized boilerplate in Count I of plaintiff's Complaint purports to assert a cause of action in strict product liability based on defective design, defective manufacture, unspecified misrepresentations, and inadequate warnings (see Complaint ¶ 47). Apparently, neither plaintiff's out-of-state lawyers nor her Pennsylvania counsel realized that there is no cause of action in strict liability against a prescription drug manufacturer under Pennsylvania law.

It is settled law in Pennsylvania that drug companies cannot be held strictly liable for their prescription drug products under either a defective product or failure to warn theory. The Pennsylvania Supreme Court has adopted and repeatedly invoked comment k of § 402A of the Restatement (Second) of Torts, which contains an exception to strict liability for manufacturers of prescription drugs. Such drugs are, by definition, considered "unavoidably unsafe." Hahn, 543 Pa. at 560-61, 673 A.2d at 890-91 (citing comment k); see also Baldino v. Castagna, 505 Pa. 239, 244, 478 A.2d 807, 810 (1984) (drug manufacturers cannot be held strictly liable for "unfortunate consequences attending the use of otherwise useful and desirable products"); Incollingo v. Ewing, 444 Pa. 263, 287, 282 A.2d 206, 219 (1971) (neither the law of Pennsylvania nor other states impose strict liability upon drug manufacturers "merely because of dangerous propensities of their product;" doing so would ill serve the public interest) (quoting in part Henderson v. Nat'l Drug Co., 343 Pa. 601, 610, 23 A.2d 743, 748 (1942)).

Like the Restatement, the Pennsylvania courts recognize that the possible unavoidable danger of prescription drugs is the very reason they are available only through prescription. "[S]uch drugs are not available to the general public but may be obtained only upon the prescriptions of a licensed physician. This restriction upon the availability of such drugs has been imposed because of the inherently dangerous properties of such drugs." Makripodis v. Merrell-Dow Pharm., Inc., 361 Pa. Super. 589, 594, 523 A.2d 374, 376 (Pa. Super. 1987).

The Pennsylvania Supreme Court made it clear in Hahn – when it reiterated its prior holdings in Baldino and Incollingo and reaffirmed the applicability of comment k and the prescription drug exception from strict liability under § 402A – that the bar against strict liability claims for prescription drugs is because of the very nature of prescription drug products:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs … [which if] properly prepared, and accompanied by proper directions and warning, [are] not defective, nor [ ] unreasonably dangerous.

Hahn, 453 Pa. at 561 n.2, 673 A.2d at 890 n.2 (quoting comment k (emphasis added)). Even more instructive is the closing remark of comment k, which states that prescription drug manufacturers are "not to be held strictly liable for unfortunate consequences" merely because the manufacturer has supplied the public with a "useful and desirable product" that has reasonable risks associated with it. See Restatement (Second) of Torts § 402A, comment k. Pennsylvania law under the unbroken line of cases – from Incollingo in 1971 to Hahn in 1996 to recent decisions from the Pennsylvania trial courts[7] – is clear that negligence, not strict liability, is the only recognized basis of liability against manufacturers of prescription drugs. Count I of the Complaint is thus fatally and incurably deficient and must be dismissed.

2. Plaintiff Cannot Establish A Negligence Claim As A Matter Of Law (Count II)

Although negligence principles define a drug manufacturer's duty, plaintiff has failed to state a claim for negligence in Count II of her Complaint. First, her boilerplate allegations make it impossible to divine the foundation of her negligence claim. Plaintiff does not describe any action that Wyeth should have taken with respect to Prempro™. And she does not allege what, if anything, Wyeth should have, but did not, communicate regarding Prempro™.

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[7] See, e.g., Luke v. American Home Prods. Corp., 1998 WL 1781624 (Northampton CCP 1998) (plaintiff's "sole recourse," if any, lies in negligence, not strict liability); In re Phen-Fen Litigation, No. 9905-0001 (Phila. CCP) (Judge O'Keefe), Order of Court dated October 13, 1999; Roof v. American Home Prods. Corp., No. 9903-0736 (Phila. CCP) (Judge Dembe), Order of Court dated July 15, 1999; Bonner v. Funches, No. 9803-4707 (Phila. CCP) (Judge Ackerman), Order of Court dated April 15, 1999.

Moreover, even if plaintiff had set forth some failure on the part of Wyeth, she could not recover under a negligence theory because she has no personal injury and the purely economic losses she claims – even if she had them – are not recoverable in tort.

a. Plaintiff Makes No Allegations Sufficient To Support A Claim For Negligence

To establish a cause of action for negligence under Pennsylvania law, plaintiff must demonstrate that Wyeth owed a duty of care to her, that Wyeth breached that duty, that Wyeth's breach caused her injury, and that she suffered an actual loss or damage. Brisbine v. Outside in Sch. of Experiential Ed. Inc., 799 A.2d 89, 93 (Pa. Super. 2002). More specifically, because she is a patient suing a prescription drug manufacturer for negligence, the only claim she could theoretically assert is that Wyeth negligently failed to provide her doctor, who prescribed Prempro™, with adequate warnings of the drug's potential dangers. See Hahn, 543 Pa. at 563, 673 A.2d at 891; Makripodis, 361 Pa. Super. at 596, 523 A.2d at 377; Demmler v. SmithKline Beecham Corp., 448 Pa. Super. 425, 433, 671 A.2d 1151, 1155, appeal denied, 546 Pa. 655, 684 A.2d 557 (1996).

Plaintiff's negligence claim misses by a mile. It is nothing more than a rambling mish-mash of boilerplate incantations apparently extracted from other, unrelated complaints filed by other plaintiffs in other cases.[8] None of the allegations, vague though they are, apply in any respect to this case. Nowhere in her complaint does plaintiff indicate any way in which Wyeth,

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[8] Hence the puzzling accusation in ¶ 57 that Wyeth continued to market Prempro™ "when safer and more effective methods of controlling high cholesterol were available" and the false statement in ¶ 53 that Prempro™ has been withdrawn from the market. Prempro™ was never indicated as a means for controlling "high cholesterol" and Prempro™ remains an FDA-approved drug which continues to be marketed.

the manufacturer in this case, could have been negligent. Her claim is that information was released by NIH about Prempro™ for the first time in July 2002 as part of a data review of a study of long-term Prempro™ use in post-menopausal women (Complaint ¶¶ 13, 18). As a result of the data, the study was discontinued (Complaint ¶ 25). Plaintiff never alleges – nor could she – that Wyeth had knowledge of the study data prior to July 2002. She cannot assert even one action that Wyeth should have taken but did not take in reaction to data that plaintiff admits was not available to Wyeth until July 2002.

Without even the vaguest indication of the manner in which Wyeth breached any duties it might have, plaintiff's negligence claim is fatally deficient. Moreover, even if plaintiff had been able to manufacture some breach on Wyeth's part, her negligence claim would fail (with all of her other claims) because she has no injury, as set forth above, and her alleged "economic losses," as set forth below, are not recoverable in negligence. Because plaintiff cannot establish a breach linked to an injury resulting in actual damages, she cannot go forward on a negligence claim.

b. Plaintiff Cannot Recover On A Negligence Claim Because Her Only Purported Losses Are Economic

Plaintiff claims no physical injury as a result of taking Prempro™. Nor does she claim that Prempro™ failed to perform for her as she expected. She nevertheless asserts that she is entitled to a refund for amounts she presumably spent on her Prempro™ prescriptions. This does not save her negligence claim. It has "long been settled" that "'no cause of action exists for negligence that causes only economic loss.'" Lennon, 2001 WL 755944 at *2, 4 (quoting Aikens v. Baltimore & Ohio R.R. Co., 501 A.2d 277, 279 (Pa. Super. 1985) and precluding recovery of refunds for purchase of vaccine that was later withdrawn from the market); accord Werwinski v.

Ford Motor Co., 286 F.3d 661 (3d Cir. 2002); King v. Hilton-Davis, 855 F.2d 1047 (3d Cir. 1988).

Even assuming, then, that plaintiff were able to somehow allege that Wyeth acted negligently, she could not recover under her negligence claim for money she spent for her Prempro™ prescriptions. Without any personal injury or injury to property other than that which she purchased, she cannot recover in negligence and her claim in Count II must therefore be dismissed.

3. Plaintiff Has No Claim For Relief Under Pennsylvania's Unfair Trade Practice And Consumer Protection Law (Count III)

Plaintiff's boilerplate allegations in Count III that Wyeth violated "any and all state consumer protection statutes" have no factual or legal substance.[9] The complaint does not plead even the most fundamental assertions for recovery. Moreover, courts applying the UTPCPL have consistently held that it does not apply in the context of prescription drugs which are only available to consumers pursuant to a prescription written by a physician acting as a learned intermediary.

a. Plaintiff Does Not Make A Single Well-Founded Allegation In Support Of Her UTPCPL Claim

Plaintiff's claims under the UTPCPL all hinge on purported representations made by Wyeth about Prempro™. Specifically, plaintiff's allegations constitute assertions of false

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[9] Preliminarily, plaintiff is not entitled to bring claims under forty-nine separate state consumer protection statutes. Wyeth therefore addresses plaintiff's allegations only with respect to Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL") because plaintiff is a Pennsylvania resident.

advertising under 73 P.S. § 201-2(v) and (ix), and fraud under 73 P.S. § 201-2(vii).[10] Yet plaintiff does not explain, even in a cursory fashion, what advertising was made by Wyeth, what specific false representations she relied on, and how she was harmed by that reliance.

To establish a false advertising claim, plaintiff must allege that she, personally, relied on false representations by Wyeth when she decided to purchase Prempro™ and that her reliance on those false representations caused her injury. Weinberg v. Sun Co., Inc., 777 A.2d 442, 446 (Pa. 2001); Sexton v. PNC Bank, 792 A.2d 602, 607 (Pa. Super. 2002); Floyd v. Brown & Williamson Tobacco Corp., 159 F. Supp. 2d 823, 833 (E.D. Pa. 2001) (DuBois, J.). Plaintiff's fraud claim under § 201-2(4)(vii) requires even more demanding pleading and proof. Like any fraud claim, plaintiff must plead with particularity – not conclusorily – facts indicating (1) that Wyeth made a specific, false representation regarding a material fact; (2) that Wyeth knew that the representation was false; (3) that plaintiff was unaware that it was false; (4) that Wyeth made the statement with the intention that it be acted upon; and (5) that plaintiff in fact acted upon the statement to her damage. Calabria v. Newmar Corp., 1999 WL 98574 (E.D. Pa. 1999) (O'Neill, J.) (granting motion to dismiss UTPCPL fraud-based claims for failure to plead fraud with specificity).[11]

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10 Plaintiff purports to claim that Wyeth violated the UTPCPL through advertising, warranting, and representing (1) "that Prempro had benefits or characteristics that it did not actually have," and (2) "that Prempro was of a particular standard or quality when it was not" (Complaint ¶ 65). Plaintiff also claims that Wyeth defrauded her when it allegedly "advertised Prempro with the intent not to seel [sic] it as advertised, and when, in so doing, [it] concealed and suppressed facts material to the true characteristics, standards, and quality of Prempro" (id.).

11 Because she seeks recovery for purely economic losses, plaintiff's fraud-based UTPCPL claim must also be dismissed because the economic loss doctrine, discussed above, precludes recovery of such losses for fraud or negligent misrepresentation. Werwinski v. Ford Motor Co., 286 F.3d 661, 681 (3d Cir. 2002).

Plaintiff fails to plead reliance and fails to plead, even generally, any elements that would support a common law fraud claim. She does not set forth even a single representation by Wyeth, let alone an allegedly false representation.

The crux of plaintiff's complaint is that data were released by the NIH in July 2002 regarding the relative risks and benefits of Prempro™. Nowhere is it alleged that Wyeth had the data before the NIH released it. It is impossible even to extrapolate from plaintiff's allegations what Wyeth may have misrepresented to her. Moreover, plaintiff alleges that she has been using Prempro™ for "a number of years" (Complaint ¶ 4). To establish her claims for false advertising and fraud, plaintiff would have to allege that Wyeth somehow was aware of the results of the study "a number of years" before those results occurred, that it misrepresented those results to her at the time she decided to use Prempro™, and that she relied on that misrepresentation in purchasing the drug. Obviously, plaintiff has not made and could not make such allegations and she has no claim under the UTPCPL.

b. Plaintiff Cannot Assert A UTPCPL Claim Because The UTPCPL Does Not Apply To Claims By Prescription Drug Users Against Manufacturers

Plaintiff cannot cure the infirmity in her UTPCPL claim because the UTPCPL does not apply to the sale of medications that must be prescribed by a physician. The UTPCPL is intended to "provide protection . . . for the unsuspecting and innocent consumer," 152 Leg. J.H. 1648 (July 17, 1968), for economic losses and to "prohibit unlawful practices relating to trade or commerce and of the type associated with business enterprises." Foflygen v. Zemel, 420 Pa. Super. 18, 36, 615 A.2d 1345, 1354 (1992).

It is applied in the context of trade practices related to commercial transactions engaged in by consumers, including residential real estate sales, financial service transactions,

residential leases, automobile sales, individual insurance contract sales, travel promotions and charitable sweepstakes.[12] In the thirty-plus years since its enactment, the UTPCPL has never been applied in any reported decision to a claim by a prescription drug user for a refund from the manufacturer based on her new-found dissatisfaction with the drug.

The intent of the UTPCPL is to "place on more equal terms seller and consumer" in recognition of the "unequal bargaining power of opposing forces in the marketplace." Commw. v. Monumental Prop., Inc., 459 Pa. 450, 462, 329 A.2d 812, 818 (1974). The premise of the statute is that a seller has a duty to furnish a consumer with relevant and material information. How then, can it apply in the unique context of prescription drugs, where the manufacturer has no duty to provide information to the consumer and the learned intermediary physician stands between the patient and the drug company? See discussion at Section B.4 below.

Pennsylvania law is crystal clear that the duties of sellers of prescription drugs run to prescribing physicians, not directly to consumers. Plaintiff's UTPCPL claim completely ignores the status of the physician as the "learned intermediary" and the "actual consumer" when considering the adequacy of the warnings and disclosures provided with prescription drugs.

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12 See, e.g., Schroeder v. Acceleration Life Ins. Co. of Pennsylvania, 972 F.2d 41 (3d Cir. 1992) (UTPCPL applies to insurance sales); In re Smith, 866 F.2d 576 (3d Cir. 1989) (mortgage transaction falls within purview of statute); In re Fricker, 115 B.R. 809 (E.D. Pa. 1990) (UTPCPL applies to private consumer loan transactions); In re Bryant, 111 B.R. 474 (E.D. Pa. 1990) (services of real estate broker fall within purview of the UTPCPL); In re Clark, 96 B.R. 569 (E.D. Pa. 1989) (landlord/tenant matter falls within the UTPCPL); Pirozzi v. Penske Olds-Cadillac-GMC, Inc., 413 Pa. Super. 308, 605 A.2d 373, alloc. denied, 532 Pa. 665, 616 A.2d 985 (1992) (automobile sales fall within purview of UTPCPL); Gabriel v. O'Hara, 368 Pa. Super. 383, 534 A.2d 488 (1987) (residential real estate sales fall within purview of the UTPCPL); Commw. v. Pennsylvania Chiefs of Police Ass'n, Inc., 132 Pa. Commw. 186, 572 A.2d 256 (1990) (UTPCPL applies in sales of advertising space); Commw. v. Watson & Hughes Co., 128 Pa. Commw. 484, 563 A.2d 1276 (1989) (UTPCPL applicable to sweepstake solicitations by charitable organizations); Commw. v. Tolleson, 14 Pa. Commw. 164, 321 A.2d 713 (1974) (air travel club's membership sales subject to UTPCPL).

Makripodis, 361 Pa. Super. at 589, 523 A.2d at 378. Even where there has been direct-to-consumer advertising of a prescription drug, the application of the learned intermediary doctrine is not diminished. Lennon, 2001 WL 755944 at *2. The plain intent of the UTPCPL was to make "certain modest adjustments to ensure the fairness of market transactions" and not to effect any "sweeping changes in legal relationships." Monumental Prop., 459 Pa. at 458, 329 A.2d at 816.

Yet that is precisely what plaintiff is asking this Court to do here. As Judge Hogan so aptly noted in rejecting plaintiff's UTPCPL claim in Luke, allowing a UTPCPL claim against a prescription drug manufacturer would turn settled case law and established legal relationships on their heads:

> [T]o permit a cause of action under the UTPCPL in this case would effectively make a drug manufacturer the absolute guarantor of the anticipated results and effects of a prescription drug. Pennsylvania law, however, recognizes that some prescription drugs by their very nature can never be made safe. *See* Makripodis, *supra*. An inconsistency would result if we were to hold that drug manufacturers must guarantee that prescription drugs are completely safe. The premise behind the UTPCPL was not meant to engender such a result.

1998 WL 1781624 at *8; accord In re Pennsylvania Diet Drug Litig., Master Docket No. 9709-3162 (Phila. CCP Feb. 6, 1998) (dismissing the class representative's UTPCPL claim pursuant to Rule 1028(a)(4)).[13]

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13 Although Judge Levin's Order dismissing the plaintiff's UTPCPL claim (Count II of the complaint in Diet Drug Litig.) was not accompanied by an opinion, the transcript of the oral argument on the defendants' preliminary objections clearly reflects the court's conclusion that the Pennsylvania Legislature did not "intend, when they enacted this to compensate consumers for ascertainable economic losses resulting from deceptive practices in the conduct of trade or commerce, . . . to include prescription drugs." See In re Pennsylvania Diet Drug Litig., Master Docket No. 9709-3162 (Phila. CCP), Oral Argument Tr. of Feb. 6, 1998, at 29 (relevant pages included with the Order in the Appendix). As in Luke, the Diet Drug court accepted AHP's argument that "it would be absurd to impose a duty under the act on the drug company who doesn't have the duty to warn the patient when it is now well established that the party that does have the duty, the physician, is immune from any claim under the act." Id. at 27.

Plaintiff's UTPCPL claim plainly has no merit. Count III of the Complaint must be dismissed.

4. Established Pennsylvania Law Bars Plaintiff's Claims For Unjust Enrichment And Breach of Implied Warranty (Counts V And VIII)

As an alternative to her inadequate tort and statutory claims, plaintiff wants disgorgement of Wyeth's "wrongful profits, revenue and benefits" under a novel claim of unjust enrichment in Count V and seeks unspecified compensatory and punitive damages for breach of implied warranty in Count VIII.[14] Plaintiff cannot hinge this "no injury/no harm" lawsuit against Wyeth on contract-based theories of unjust enrichment or breach of implied warranty.

First, plaintiff had no dealings with Wyeth that would support a quasi-contractual or equitable claim for unjust enrichment, and she cannot point to any unjust benefit Wyeth received as a result of her purchase of Prempro™. Plaintiff got an FDA-approved prescription drug for hormone replacement therapy that her physician prescribed for her. She suffered no physical harm and does not even allege that she failed to benefit from her physician-prescribed therapy. How can it be unjust for Wyeth to retain monies derived from the sale of Prempro™ to her?

Second, the learned intermediary doctrine strikes a fatal blow to plaintiff's contract-based breach of implied warranty claim. A patient can only get prescription products through her prescribing doctor, who is the "learned intermediary" between the drug manufacturer and the patient. Because the drug manufacturer has no relationship or contact with the patient, it is the prescribing physician, not the manufacturer, who has the duty and obligation to advise and

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14 Plaintiff also makes a claim for breach of express warranty in Count VII. Wyeth addresses the inadequacy of that claim in Section B.5 below.

warn the patient of the potential dangers and side effects of the prescription drugs he chooses to prescribe. Baldino, 505 Pa. at 247, 478 A.2d at 812; White v. Weiner, 386 Pa. Super. 111, 562 A.2d 378 (1989), aff'd, 525 Pa. 572, 583 A.2d 789 (1991). The manufacturer has a duty to warn only the prescribing physician of the known adverse reactions to its prescription products. See, e.g., Hahn, 543 Pa. at 562, 673 A.2d at 890; Incollingo, 444 Pa. at 288, 282 A.2d at 220; Makripodis, 361 Pa. Super. at 596, 523 A.2d at 378; Lennon, 2001 WL 755944 at *1.

a. Plaintiff's Unjust Enrichment Claim Is Inadequate On Its Face And As A Matter Of Law

Plaintiff's novel unjust enrichment claim is replete with the same boilerplate that permeates her Complaint and is incurably deficient as a matter of law. As pled, plaintiff's unjust enrichment claim appears to rely on contract-based concepts of implied warranty of merchantability and fitness for use (see Complaint ¶ 70) that do not exist under Pennsylvania law because of the learned intermediary doctrine. "Unjust enrichment is essentially an equitable doctrine" invoked in assumpsit when a party seeks to recover a benefit conferred under an unconsummated or void contract. Mitchell v. Moore, 729 A.2d 1200, 1203 (Pa. Super. 1999) (internal citation omitted); Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 936 (3d Cir. 1999).

The doctrine of unjust enrichment does not apply simply because the defendant may have benefited from some action of the plaintiff. Wiernik v. PHH U.S. Mortgage Corp., 736 A.2d 616, 622 (Pa. Super. 1999) (dismissing unjust enrichment claim brought on behalf of class where neither contract nor common law suggested that defendants were unjustly enriched). "The mere fact that an overpayment of some sort has been demanded and payment made will not support the [unjust enrichment] action." Hall v. Humana Hosp. Daytona Beach, 686 So.2d 653, 656 (Fla. Dist. Ct. App. 1997) (dismissing class unjust enrichment claim based on overcharges

allegedly paid by class members to hospital in connection with medical services and pharmaceuticals received). In other words, unless a plaintiff can plead and show an "unjust" benefit she conferred on the defendant, she has no claim to the quasi-contractual remedy of unjust enrichment and no right to equitable relief.

Here, plaintiff's own admissions defeat her unjust enrichment claim. Plaintiff got exactly what her physician prescribed, an FDA-approved hormone replacement therapy that caused her no physical harm and which she admits has the known beneficial effects of reducing the incidence of post-menopausal symptoms, hip fractures, and colorectal cancer.

There is nothing unjust in Wyeth's retention of any benefit it may have derived from plaintiff's purchase of Prempro™. She is not entitled to get her money back under any theory of unjust enrichment, and Count V of the Complaint should be dismissed.

b. Pennsylvania Law Does Not Recognize An Implied Warranty For A Prescription Drug

An ever-expanding legion of case law conclusively defeats plaintiff's implied warranty claim in Count VIII. The cases uniformly rely on the learned intermediary doctrine and consistently reject, as a matter of law, efforts to imply a warranty of merchantability or fitness for use of prescription drugs. Pennsylvania law is clear that no implied warranty may arise from the sale of a prescription drug.

As the Superior Court explained in Makripodis, the very nature of prescription drugs, combined with the individual characteristics of the person for whom they are prescribed, "precludes imposition of a warranty of fitness for 'ordinary purposes.'" 361 Pa. Super. at 594, 523 A.2d at 376-77. Each patient is a "unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient." Id.; see also Henderson, 343 Pa. 601, 23 A.2d 743; Lewis v. Geisinger Med. Ctr., 43 Pa.

D. & C.2d 105, 114 (Phila. CCP 1967) (rejecting claims against drug manufacturers for breach of express and implied warranties in action alleging injuries from use of prescription drugs).

Although Makripodis was decided in the context of a pharmacist's liability, the Superior Court made clear that its holding and rationale were not so limited. The rationale that precludes recognition of an implied warranty of merchantability for a prescription drug derives from comment k to § 402A. The court's rationale and holding depend not on the identity of the defendant, but on the recognition that prescription drugs, by their very nature, fall into that category of products that are "incapable of being made safe for their intended and ordinary use." Makripodis, 361 Pa. Super. at 594, 523 A.2d at 376-77 (quoting comment k) (emphasis added).

Recent cases from this court and the Pennsylvania trial courts have followed Makripodis to reject breach of implied warranty claims against prescription drug manufacturers. Luke, 1998 WL 1781624 at *6; Laster v. A.H. Robins Co. Inc., No. 99-05734 (Chester CCP), Order dated Oct. 28, 1999, at n.1; Reger v. A.H. Robins Co., Inc., No. 98-7942-23-2 (Bucks CCP), Order dated May 27, 1999; Murray v. Synthes (U.S.A.), Inc., 1999 WL 672937 at *9 (E.D. Pa. 1999); Burton v. Danek Med., Inc., 1999 WL 118020 at *7 (E.D. Pa. 1999); Taylor v. Danek Med., Inc., 1998 WL 962062 at *14 (E.D. Pa. 1998); see cases cited in note 7 *supra*.

This pervasive and binding authority establishes the futility of plaintiff's implied warranty claim and mandates dismissal of Count VIII as a matter of law.

5. Plaintiff Does Not And Cannot Plead A Cognizable Express Warranty Claim (Count VII)

Plaintiff's claim for breach of an express warranty in Count VII, like all of the others, consists of nothing more than general boilerplate. She fails to plead the essential elements of an express warranty much less a case for breach of warranty. Presumably, plaintiff purports to make a claim under the UCC express warranty provisions (13 Pa. C.S.A. § 2313

(2002)), but, in violation of those provisions, she fails to plead any actual affirmations of fact or promises which related to Prempro™, and which became part of the basis of her bargain in her decision to purchase Prempro™. Moreover, as discussed throughout this brief, even if plaintiff had pled the elements of an express warranty or a breach of that particular warranty, she has not pled any damages flowing from that breach.

The sum and substance of plaintiff's express warranty claim is that Wyeth made unspecified express warranties "orally and in publications, package inserts and other written materials intended for physicians, medical patients, and the general public that Prempro™ was safe, effective, fit, and proper for its intended use," that the warranties were false, and that plaintiff relied on them (Complaint ¶¶ 80–81). The Court need only take the single word "Prempro™" out of paragraphs 80 and 81 to appreciate that these allegations could apply to *any* product and that this purported "express" warranty claim is anything but express; it is completely vague and incapable of comprehension.

Plaintiff does not identify a single express warranty that was allegedly directed to her and on which she allegedly relied because she cannot. She does not even allege why she was prescribed and was taking Prempro™. And, of course, she admits that Prempro™ did not cause her any injury or harm. On its face and in substance, plaintiff's claim for breach of express warranty in Count VII is palpably inadequate and should be dismissed as a matter of law.

6. Plaintiff Does Not And Cannot Allege The Fundamental Prerequisites To A Medical Monitoring Claim Under Pennsylvania Law (Count VI)

In their haste to be first, plaintiff and her lawyers have overlooked – or purposely ignored – that her claim in Count VI of the Complaint does not fit even the most basic elements of a claim for medical monitoring under Pennsylvania law.

Pennsylvania recognizes a limited cause of action for medical monitoring. See Redland Soccer Club, 696 A.2d at 145-46. A plaintiff who seeks to require a defendant to pay for her future "medical monitoring" must plead and prove all of the following seven criteria:

(1) exposure greater than normal background levels;

(2) to a proven hazardous substance;

(3) caused by the defendant's negligence;

(4) a significantly increased risk to her of contracting a serious latent disease as a proximate result of the exposure;

(5) a monitoring procedure that makes the early detection of the disease possible;

(6) a prescribed monitoring regimen that is different from that normally recommended in the absence of the exposure; and

(7) a prescribed monitoring regimen that is reasonably necessary according to contemporary scientific principles.

Id. at 145-46; accord Barnes v. The American Tobacco Co., 161 F.3d at 138-39.

At the pleading stage, it is clear that plaintiff's medical monitoring claim must be dismissed on at least three grounds: (a) her failure and inability to allege exposure caused by defendant's negligence, (b) her failure and inability to allege that she has a "significantly increased risk of contracting a serious latent disease," and (c) her failure and inability to plead a monitoring regimen that is "different from that normally recommended in the absence of the exposure." Redland, 696 A.2d at 145-46.

a. Plaintiff Does Not And Cannot Allege "Exposure" To Prempro™ As A Result Of Negligence By Wyeth

As Wyeth details in the earlier sections of this Brief, it is clear from plaintiff's boilerplate Complaint that she has no claim in negligence against Wyeth. This is a fundamental and fatal flaw that requires dismissal of her medical monitoring claim as a matter of law. See

Wagner v. Anzon, Inc., 453 Pa. Super. 619, 631, 684 A.2d 570, 576 (1996); Cull v. Cabot Corp., 2001 WL 517302 (Phila. CCP 2001) ("a defendant's negligence is an essential element of a medical monitoring claim. This is especially true given the limited recognition of medical monitoring as a cause of action"); see also Hansen v. Mountain Fuel Sup. Co., 858 P.2d 970, 979 (Utah 1993) ("the plaintiff must prove that the exposure to the toxic substance was caused by the defendant's negligence, i.e., by the breach of a duty owed to the plaintiff").

Wyeth's duty under well-established Pennsylvania law was reasonably to inform prescribing physicians of risks of which Wyeth knew or about which it should have been aware. See Makripodis, 361 Pa. Super. at 378, 523 A.2d at 596. Plaintiff does not, and could not, allege that Wyeth previously knew or could have known of information that was only first available when the results of the WHI study were made public.

Indeed, allegations of the Complaint affirmatively negate any negligence on Wyeth's part. See Complaint ¶¶ 17-18 (acknowledging that prior to the new NIH data, there was no indication or signal of any increased risk, and that the study data on which her case is built have just been realized "for the first time"). On their face and in substance, these allegations are insufficient as a matter of law to support plaintiff's claim for medical monitoring. As Judge Scirica wrote in Barnes, "[i]n order to prevail on their medical monitoring . . . plaintiffs must demonstrate that defendants caused their exposure to tobacco. . . . [B]ut plaintiffs cannot prove causation by merely showing that smoking cigarettes causes cancer and other diseases." 161 F.3d at 144-45 (emphasis added). Plaintiff has not adequately alleged that her exposure to Prempro™ was due to Wyeth's negligence and that alone bars her medical monitoring claim.

b. Plaintiff Fails To And Cannot Allege That She Is At Any Significantly Increased Risk Of Harm

Plaintiff has not alleged that she is at any, much less a significant, increased risk of harm due to her ingestion of Prempro™. To the contrary, all she has alleged is that she "may" be at some degree of increased risk of injury (Complaint ¶ 4). Such an allegation is plainly inadequate under the Redland criteria.

Even if plaintiff were to allege – which she has not – that other persons are at "significantly increased risk," her own failure to allege that she is would require dismissal of her medical monitoring claim. But it is also clear, based on the data on which plaintiff relies in her Complaint, that no Prempro™ users are at the sort of increased risk which could justify medical monitoring relief. As to other members of the putative class, the Complaint acknowledges that the risk to each of them is "low" (id. at ¶ 20). Indeed, the absolute and relative risk data quoted in the Complaint make it clear that whatever degree of risk Prempro™ users face for breast cancer, stroke, heart attacks or blood clots, is (a) very small and (b) predominantly due to factors other than Prempro™. On breast cancer, for example, the data set forth in paragraphs 20-25 of the Complaint suggest that if 10,000 women used Prempro™, 38 would get breast cancer, 30 of whom would simply represent a background rate. In other words, according to the Complaint, the use of Prempro™ might increase a woman's risk of breast cancer from .30 of 1% to .38 of 1%, an increase in the actual risk of eight one-hundredths of 1%. On that sliver of added risk, plaintiff would require defendant to pay perpetually for the monitoring of millions of women, even though the great majority of the cases which might be detected in any given year would have no relationship whatsoever to any conduct of the defendant.

In the absence of proof that there is a "significant" increased risk of contracting a serious disease, courts have routinely denied broad claims for medical monitoring damages. See,

e.g., O'Neal v. Dep't of the Army, 852 F. Supp. 327, 328 n.8 (E.D. Pa. 1994) (increased risk of .03% held to be insufficient); Heller v. Shaw Indus., Inc., 1997 WL 535163 (E.D. Pa. 1997), aff'd, 167 F.3d 146 (3d Cir. 1999); In re Paoli R.R. Yard PCB Litig., 2000 WL 274262 (E.D. Pa. 2000); Abuan v. General Elec. Co., 3 F.3d 329 (9th Cir. 1993) (granting summary judgment on medical monitoring claim where experts could not quantify increased risk of serious disease as "substantial"); Lilley v. Board of Supervisors of Louisiana State Univ. & Agric. & Mech. Coll., 735 So. 2d 696, 705-06 (La. Ct. App. 1999).

Plaintiff's failure to allege, as required by Redland, that she has a "significantly increased risk" of suffering a serious latent disease bars the medical monitoring relief she seeks.

c. Plaintiff Does Not And Cannot Allege The Need For Any Monitoring That Is Different From What Would Otherwise Be Prescribed For Post-Menopausal Women

A claim for medical monitoring requires a party to show "that the monitoring program he requires is different from that normally recommended in the absence of exposure." Barnes, *supra*, 161 F.3d at 146 (citing Redland Soccer, 696 A.2d at 146). Plaintiff does not allege – nor could she – that whatever monitoring program she is seeking would be different from that normally recommended for Prempro™ users, i.e., for menopausal women, in the absence of Prempro™.

This is a fatal and incurable defect in her claim for medical monitoring. See, e.g., Redland Soccer Club v. Dep't of the Army, 55 F.3d at 827 (3d Cir. 1995) (affirming summary judgment on medical monitoring claims where plaintiffs failed to introduce evidence that their exposure required different medical monitoring regimen than that which would normally be recommended for them absent exposure); In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 788 (3d Cir. 1994) (plaintiff may recover only if defendant's wrongful acts increased plaintiff's

incremental risk of incurring the harm enough to "warrant a change in the medical monitoring that otherwise would be prescribed for that plaintiff") (internal citations omitted); Arch v. American Tobacco Co., 175 F.R.D. 469, 490 (E.D. Pa. 1997) ("The fact that [plaintiff] smokes would not require any additional monitoring for heart disease not already warranted by the multiple, significant risk factors for heart disease he already has."); Heller v. Shaw Indus., Inc., 1997 WL 535163, aff'd, 167 F.3d 146 (3d Cir. 1999) (granting summary judgment on medical monitoring claim where plaintiffs failed to show that "increased risks of harm caused by their exposure to toxic substances warrant a change in the medical monitoring that otherwise would be prescribed for [them]."); In re Paoli R.R. Yard PCB Litig., 2000 WL 274262 (denying plaintiff's motion for reconsideration on the exclusion of expert testimony regarding medical monitoring because, *inter alia*, monitoring protocol was the same as what would be recommended for any person, regardless of alleged chemical exposure); Miranda v. Shell Oil Co., 17 Cal. App. 4th 1651, 1660 (1993) ("a toxic tort plaintiff may not recover for preventative medical care and checkups to which members of the public at large should prudently submit"); Hansen, 858 P.2d at 980 ("plaintiff may recover [for medical monitoring] only if the defendant's wrongful acts increased the plaintiff's incremental risk of incurring the harm produced by the toxic substance enough to warrant a change in the medical monitoring that otherwise would be prescribed for that plaintiff, a change that would represent increased costs to the plaintiff"); Potter v. Firestone Tire and Rubber Co., 863 P.2d 795, 825 (Cal. 1993) (plaintiffs may recover for medical monitoring "only if the evidence establishes the necessity, as a direct consequence of the exposure in issue, for specific monitoring beyond that which an individual should pursue as a matter of general good sense and foresight").

Plaintiff alleges only that "monitoring and testing procedures exist which make the early detection and treatment of disease possible and beneficial" (Complaint ¶ 76). She refrains from alleging, however, that such procedures are any different from those recommended for women of menopausal age as part of a regular monitoring program. This is not a mere oversight or pleading deficiency. The Report of the U.S. Preventive Services Task Force ("USPSTF"), published in Guide to Clinical Preventive Services, 2d ed. (1996), for example, notes that the American Cancer Society, American College of Radiology, American Medical Association, American College of Obstetricians and Gynecologists, as well as a number of other organizations, recommend annual screening with mammography and a clinical breast exam for all women beginning at age 50. Id. at p. 81.[15] The U.S. Department of Health and Human Services recently reaffirmed the USPSTF guidelines extending the routine mammography recommendation to all women over the age of 40. See HHS Press Release dated Feb. 21, 2002, attached hereto as Exhibit C.

Because plaintiff has utterly failed to describe the monitoring program she thinks is required and because she has further failed to allege that it differs in any way from that normally recommended for women of menopausal age, her medical monitoring claim must be dismissed.

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15 These guidelines are cited in Paoli, 2000 WL 274262 at *8, as a "widely recognized and authoritative source." Copies of the pertinent sections of the Guidelines are attached hereto as Exhibit B. Wyeth is permitted to attach these public records to this Motion to Dismiss without converting the motion to a summary judgment motion, as they are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." See cases cited at n.4, *supra*.

III. CONCLUSION

For all the reasons set forth above, the Complaint in this case fails to state any cause of action upon which relief could be granted. Accordingly, the Complaint should be dismissed.

Respectfully submitted,

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DATED: July 24, 2002

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Defendant Wyeth's Motion to Dismiss the Complaint of Plaintiff June Bloch for Failure to State a Claim and accompanying Memorandum of Law in Support has been served by first-class mail, postage prepaid, this 24th day of July, 2002, on the following counsel of record:

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